ISRCTN24909354 https://doi.org/10.1186/ISRCTN24909354

Phase I trial: Parexel Code: PXL277433

Submission date 15/11/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 16/11/2023	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 16/11/2023	**Condition category** Other	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr David Steel

Contact details
Parexel Early Phase Clinical Unit (LONDON)
Northwick Park Hospital
Level 7
Watford Road
Harrow
London
United Kingdom
HA1 3UJ
+44 (0)7548098654
david.steel@parexel.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1007366

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
IRAS 1007366, Parexel PXL27743

Study information

Scientific Title
Phase I trial: Parexel Code: PXL277433 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 02/08/2023, Brent Research Ethics Committee Health Research Authority (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8128, +44 (0)207 104 8131; brent.rec@hra.nhs.uk), ref: 23/LO/0321; The HRA has approved deferral of publication of trial details.

2. Approved 17/08/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 29969/0159/001-0001; The HRA has approved deferral of publication of trial details

Study design
First-in-man safety, pharmacokinetics and pharmacodynamics trial in 88 healthy volunteers

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Safety

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied

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Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic, Safety

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Secondary outcome measures
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Overall study start date
15/05/2023

Completion date
30/08/2024

Eligibility

Key inclusion criteria
Healthy human volunteers

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
88

Key exclusion criteria
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Date of first enrolment
22/08/2023

Date of final enrolment
30/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Parexel International; Parexel Early Phase Clinical Unit
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Sanofi-Aventis Recherche & Développement

Sponsor details

1 avenue Pierre Brossolette
Chilly-Mazarin
France
91380
-
uk-medicalinformation@sanofi.com

Sponsor type
Industry

Website
https://www.sanofi.co.uk/en/contact

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis Recherche & Développement

Results and Publications

Publication and dissemination plan
Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date
02/03/2027

Individual participant data (IPD) sharing plan
Qualified researchers may request access to patient-level data and related study documents including the clinical study report, study protocol with any amendments, blank case report form, statistical analysis plan, and dataset specifications. Patient-level data will be anonymized and study documents will be redacted to protect the privacy of trial participants. Further details on Sanofi's data sharing criteria, eligible studies, and process for requesting access can be found at: https://vivli.org

IPD sharing plan summary
Available on request